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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,011	10/23/2000	Feng Yan	1889-34	8985

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/694,011

Applicant(s)

YAN ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment filed on December 17, 2002 has been entered. Claims 76-79 are now pending. Any rejection that is not addressed in this Office Action is considered obviated in view of Applicant's claim Amendments and the respective Arguments ("Response"). The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

2. Applicant's arguments with respect to priority have been fully considered and are found partially persuasive. Accordingly, the effective priority of this application appears to follow the 09/021,367 chain of applications that is November 30, 1994, because the disclosure of such set of applications are sufficiently disclose a mixture of phosphatidic acid, air and perfluorobutane in preparing an ultrasound contrast agent. At best Applicant may be entitled to an effective filing date of December 15, 1993. Examiner requests a copy of priority documents to properly address priority benefits under 35 U.S.C. 119(a)-(d).

3. Applicants assert entitlement to priority date of January 24, 1992, the filing date of EP 92810046.0 (Response at p.8). However, aside from the priority chain of the application 09/021,367, all other chains of applications from which priority has been claimed do not properly meet the written description requirements under 35 U.S.C. 112, first paragraph.

4. Examiner points out that the first paragraph of 25 USC 112 requires that the "specification shall contain a written description of the invention." This requirement is

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separate and distinct from the enablement requirement. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). Accordingly, "the essential goal of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Under this requirement, "[o]ne shows that one is "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious." *Lockwood v. American Airlines Inc.*, 107 F3d 1565, 1574, 41 USPQ2d 1961, 1967 (Fed Cir. 1997). The instant application fails to meet such requirements.

5. As the initial matter, Examiner states that the elected species require a mixture of air, perfluorobutane and phosphatidic acid. Application SN 10/061,299 and its priority chain claiming the benefit of EP 92810046.0 filed January 24, 1992 does not adequately show that Applicants were "in possession" of the claimed invention by describing the invention with all its claimed limitation. There are neither an explicit nor an implicit teaching supporting the entire scope of instant methods.

6. Applicant's assertion at best amounts to an obviousness-type conclusion, which even if proven, does not satisfy the written requirement under 112 1st paragraph. In effect, Applicant appears to be arguing that it would have been obvious to one of skilled in the art at the time of filing of the parent cases that Applicant had possession of the instantly claimed methodology. However, Examiner sets forth that it is well settled in the Patent Law that "[E]ntitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to

that which is disclosed. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification." *Lockwood vs. American Airlines Inc.*, 107 F3d 1565, 1572.

7. As reasoned in *Lockwood*, the question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and does so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. See *Martin v. Mayer*, 823 F.2d 500, 504, 3 U.S.P.Q.2D (BNA) 1333, 1337 (Fed. Cir. 1987) (stating that it is "not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure Rather, it is a question whether the application necessarily discloses that particular device.") (quoting *Jepson v. Coleman*, 50 C.C.P.A. 1051, 314 F.2d 533, 536, 136 U.S.P.Q. (BNA) 647, 649-50 (CCPA 1963)). A description, which renders obvious the invention for which an earlier filing date is sought, is not sufficient. *Id.* Therefore, to claim priority one must show that he or she is "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious.

8. Thus, nowhere in the parent applications; 08/855,055 and its chain of priority, 09/706,788 and its chain of priority, and 09/630,537 and its chain of priority, is there a clear indication that Applicant was "in possession" of the invention at the time of filing. Therefore, the effective priority date of the instant application is either November 30, 1994 or December 15, 1993.

Double Patenting

9. Claims 25-26, 34, 37, 41-46 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of US Patent 5,597,549, claims 1-12 of US Patent 5,445,813, claims 11-13 of US Patent 5,271,928, claims 10-16 of US Patent 5,643,553 for the reasons of record.

10. Claims 25-26, 34, 37, 41-46 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 09/748,120, claims 16, 34-36, 44, 71-72; copending Application No. 09/770216, claims 35-36; copending Application No. 09/401,836 claims 18-25; copending Application No. 09/401,835, claims 4-9; copending Application No. 09/736,361, claims 11-22.

Per Applicant's request (Response at p. 13) these rejections are held in abeyance until the claims are indicated to be allowable.

Claim Rejections - 35 USC § 103

11. Claims 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schutt in view of Unger US Patent 5,585,112.

12. Applicant's arguments have been fully considered but are not found persuasive. Applicant first argues that neither Schutt nor Unger are competent prior art because they have a filing date which is later than the instant application.

13. In response, Examiner states that as argued above the effective priority date of instant application is either November 30, 1994 or December 15, 1993. Accordingly, both Schutt and Unger are competent prior art. More specifically, Unger's priority is at

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least as early as Jun 18, 1991. As stated in previous Office Action, Unger is relied upon its teaching that ultrasonic contrast agents can be made of liposomes with a phosphatidic acid moiety (see examples 4-5, claim 21). This teaching has been properly disclosed in Unger Application 07/0717,084 which became US Patent 5,228,446, a copy of which is hereby attached. In that patent, Unger taught the use of saturated phospholipids as film forming material. Such phospholipids included phosphatidylcholine and phosphatidic acid (see col 6, lines 5-7 and col 14, lines 53-56). Accordingly, the use of phosphatidic acid was well disclosed by Unger in his US Patent 5,585,112, because it properly claimed priority to his earlier US Patent 5,228,446. Therefore, Unger is a competent prior art.

Schutt is also competent prior art for the reasons set forth earlier in the priority section. Therefore, the combined teachings of Schutt and Unger have been properly applied.

14. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is found within references themselves.

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15. Schutt, for example, teach the combination of a first gas such as air and a second osmotic gas such as perfluorobutane surrounded by a membrane such as a phospholipid surfactant (see abstract; col 3, lines 40-67; col 4, lines 1-5, col 12, line 17-20; col 15, lines 44-63; col 16, lines 56-65; examples III-VI; claims 1-23). Schutt only lacks the specific use of surfactants containing phosphatidic acids. This deficit is taught in Unger. Unger readily uses phosphatidic acid as a film forming moiety to form his liposomes. (see examples 4-5, claim 21). Thus, using phosphatidic acid as Schutt's phospholipid would have been obvious because to any suitable phospholipid such as phosphatidic acid, because as taught by Unger, the ordinary skill in the art would have had a reasonable expectation of success in formulating stable gas carrying liposomes suitable for ultrasound imaging.

16. Applicant also argues that Schutt relies on choice of gases to control the osmotic pressure while Unger relies on the liposomal structure for stability and that changes the principle of operation of the references. It is not clear how such conclusion is drawn, nevertheless, Unger at col 26, lines 9-35, explicitly suggests the use of gas mixtures in his formulations. Accordingly, there is ample support in both references to combine air and perfluorobutane in a gaseous microbubble.

17. Finally, Applicant argues that the cited combination does not yield applicant's claimed invention. In reply Examiner restates that "[T]he fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter.

1985). In the instant case, all elements of the claimed invention are taught by the combined teachings of Schutt and Unger. Accordingly, the scope of the instant pending claims have been properly rejected.

18. Claims 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schutt in view of Unger US Patent 5,228,446.

The teachings of Schutt are discussed above. Schutt does not teach the use of phosphatidic acid as a film forming surfactant.

Unger teaches that phosphotidic acid can be employed to form gaseous liposomes. (col 6, lines 1-30; col 14, lines 18-32).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to employ phosphatidic acid as the phosholipid of choice in Schutt's formulations, because as taught by Schutt himself phospholipids maybe used as surfactants and further as taught by Unger, the ordinary artisan would have had a reasonable expectation of success in using such phospholipids as phosphotidic acid to formulate gaseous ultrasonic contrast agents.

Conclusion

19. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
March 17, 2003


RUSSEL TRAVERS
PRIMARY EXAMINER
GROUP 1200